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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/658,823

09/08/2003

Shawn DeFrees

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07/25/2006

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EXAMINER

SHEN, BIN

ART UNIT

PAPER NUMBER

1655

DATE MAILED: 07/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/658,823

Applicant(s)

DEFREES, SHAWN

Examiner

Bin Shen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 36-50 is/are pending in the application.
- 4a) Of the above claim(s) 41,42,45,46 and 48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-40,43,44, 47,49,50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____  |

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**DETAILED ACTION**

***Election***

Applicant's election of species with traverse of

A(ii) A method of determining glycosyltransferase activity using a labeled substrate or acceptor;

A(ii)(2) A fluorescent label;

B(i) A fucosyltransferases;

C(i) A test compound comprising an aromatic ring structure;

C(i)(2) heteroaryl moiety; and

Provisional election of claim 50 species: carbazole.

in the reply filed on 5/15/2006 is acknowledged. The traversal is on the ground(s) that the Examiner has not provided the particular reasons relied on for holding that the invention as claimed are patentably distinct. This is not found persuasive because the Examiner provided reasons for election of species (see Office Action mailed on 3/15/2006, page 2, lines 9-10 and 18-19, page 3, lines 5-7 and 15-16, page 4, lines 1-2).

The IDS received 12/23/2004 and 5/19/2006, the preliminary amendment received 9/8/2003 have been entered.

Claims 41, 42, 45, 46, 48 are considered nonelected because they are drawn to nonelected species and thus are withdrawn from further consideration.

Only claims 36-40, 43, 44, 47, 49 and 50 are presented for examination on the merits.

The requirement is still deemed proper and is therefore made FINAL.

***Claim Rejections - 35 USC § 103***

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36-40, 43, 44, 47, 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Qiao et al (J Am Chem Soc 1996;118:7653-7662), in view of Rabina et al. (Analytical Biochem 1997;246:71-78), Sousa et al. (Cell Mol Biol 1996;42: 609-616), and Chung et al. (Bioorg & Med Chem Let 1998;8:3359-3364).

Qiao et al. teach a method of identifying an inhibitor of a fucosyltransferase (see abstract and Fig. 6) and that fucosylation is the last and critical step of glycosylation and inhibitors of fucosyltransferase are potentially useful as anti-inflammation and anti-tumor agents (Introduction, 1<sup>st</sup> paragraph), and the construction and testing of fucosyltransferase specific inhibitors (page 7654, right column, 1<sup>st</sup> full paragraph).

Qiao does not teach a donor substrate with a hydrophobic, non-carbohydrate test compound, the use of an antibody to determine fucosyltransferase activity in an ELISA format, expression of fucosyltransferase in recombinant cell and the labeling of donor or acceptor substrate with fluorescent.

Rabina et al. teach an immunofluorometric method to measure a fucosyltransferase activity by incubating fucose donor and acceptor with enzyme source prepared from extract of recombinant cell that express the enzyme (see abstract and Materials and

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Methods 4<sup>th</sup> and 5<sup>th</sup> paragraph); the fucosylated reaction product is detected and quantified using a product-specific primary antibody (see page 72, 2<sup>nd</sup> full paragraph); this time-resolved fluoroimmunoassay method (with microtiter strip wells-read as an ELISA format) provide over 25-fold higher sensitivity than ELISA (see page 76, middle of 2<sup>nd</sup> full paragraph).

Sousa et al. teach that hydrophobic amino acids in the active site of glucosyltransferase forms part of the recognition mechanism for the enzyme activity (see abstract).

Chung et al. teach that incorporation of an appropriate aromatic group to the aglycon position of the enzyme, an inhibitor developed on the basis of a proposed active site model of the enzyme, results in strong inhibition (see abstract and page 3362, 2<sup>nd</sup> paragraph)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of Qiao to identify an inhibitor of a fucosyltransferase with a fluorescent labeled substrate and a hydrophobic test compound with aromatic ring structure (such as with a heteroaryl moiety-carbazole) because Qiao et al. teach the importance of fucosyltransferase inhibitor in inflammatory process and tumor development (Introduction, 2<sup>nd</sup> paragraph) and Rabina teach a immunofluorometric method for measurement of fucosyltransferase activity. One would have been motivated to make the modification because Sousa teach that hydrophobic amino acids in the active site of glucosyltransferase forms part of the recognition mechanism for the enzyme activity and Chung teach the development of inhibitors based on the proposed active site model of the enzyme (see page 3362, 2<sup>nd</sup> paragraph), and would reasonably have expected success in view of Sousa and Chung's

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teaching because they not only teach the importance of glycosyltransferase inhibitors but also how to identify new inhibitors with strong enzyme activity inhibition based on the structure of the enzyme active site (using of hydrophobic test compound to inhibit interaction of a sugar with hydrophobic amino acids in the active site of the enzyme). The labeling of substrate with fluorescent is deemed merely a matter of judicious selection and routine optimization to eliminate unnecessary step to speed up the assay in view of Rabina's teaching where fluorescent labeled secondary antibody are used, which is well within the purview of the skilled artisan having the cited reference before him/her.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### **Conclusion**

No claim is allowed.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO

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DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Bin Shen, Ph.D., whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday

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through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to her office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey can be reached at (571) 272-0775.



**MICHAEL MELLER**  
**PRIMARY EXAMINER**

*B Shen*

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